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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,759	12/21/2004	Takekuni Nakama	58777.000017	2877

21967 7590 12/28/2007

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,759	NAKAMA, TAKEKUNI	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/5/2007 has been entered.

2. In the response received on 10/5/2007, the Applicant cancelled claims 9, 12, 13, and 16, and added new claims 18-21. Therefore, claims 14-15 and 17-21 are currently pending and are the subject of this office action.

Rejections withdrawn

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claims 14-15 and 17 under 35 USC § 112, second paragraph, as being indefinite regarding the term JRU, as set forth on page 3 of the office action mailed on 4/5/2007 and page 6 of the office action mailed on 11/30/2006, is *withdrawn* in response to Applicant's amendments to the claims to define the term JRU as "Japanese Reference Units".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of claims 14-15 and 17 under 35 USC § 102(b) as being anticipated by Tara *et al* ("Tara" - US 5,171,567), as set forth on pages 4-5 of the office action mailed on 4/5/2007, is *withdrawn* in response to Applicant's amendments to the claims to recite a method of treating a human "patient in need of such treatment", wherein said method comprises intravenous administration of interferon (IFN)-gamma. The Applicant argues that Tara does not meet each limitation of the claims as currently amended because Tara does not teach intravenous administration of IFN-gamma. These arguments have been fully considered and are persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Rejection of claims 14-15 and 17 under 35 USC § 103(a) as being obvious in view of the combination of Shachar *et al* ("Shachar" – US 20030053985) and Tara *et al* ("Tara" – US 5,171,567), as set forth on pages 5-7 of the office action mailed on 4/5/2007, is *withdrawn*.

The claims are drawn to a method of treating bullous pemphigoid comprising administering to a human patient in need of such treatment a daily intravenous dose of IFN-gamma of 2,000,000 – 4,000,000 JRU. The claims further recite administering IFN-gamma in combination with an antihistaminic, an antiallergic, or corticosteroid, or any combination thereof, and administration for seven consecutive days.

Shachar teaches parenteral administration of IFN-gamma for treatment of inflammatory disorders, including bullous pemphigoid (paragraphs 0053 and 0204, and claims 23 and 87). Tara discloses administration of a composition of IFN-gamma at 1,000,000 to 6,000,000 JRU, which can be co-administered with a corticosteroid.

In the response received on 10/5/2007, the Applicant argue that the claimed invention is not obvious in view of Shachar and Tara because Shachar teaches that administration of high doses of IFN-gamma produces unwanted, severe side-effects. Furthermore, Sharchar is directed towards treatment of

inflammation in general, and Tara teaches treatment of adult T cell leukemia/lymphoma, and neither reference teaches intravenous administration of IFN-gamma.

These results have been fully considered and are found persuasive in light of Applicants arguments that a person of ordinary skill in the art would not be motivated to administer the claimed doses of IFN-gamma in view of the teachings of Shachar regarding severe side-effects of high dose IFN-gamma administration.

New Grounds of Rejection

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-15 and 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of treating bullous pemphigoid comprising administering to a human patient in need of such treatment a daily intravenous dose of IFN-gamma of 2,000,000 – 4,000,000 JRU. The claims further recite administering IFN-gamma in combination with an antihistaminic, an antiallergic, or corticosteroid, or any combination thereof, and administration for seven consecutive days.

It is known in the art that administration of IFN-gamma results in unwanted, severe side-effects. Shachar (cited in the previous office action), teaches that administration of high doses of IFN-gamma results in "unacceptably severe side-effects in patients", including fever and chills, anorexia and fatigue, nausea and vomiting, leukopenia, and abnormal liver functions, which limits the therapeutic desirability of high-dose IFN-gamma therapy (see paragraphs 0025-0028). Furthermore, Shachar teaches that administration of 33,000 and 15,000 units of IFN-gamma per kilogram body weight for treatment of idiopathic pulmonary fibrosis and Crohn's disease, respectively, resulted in side effects "of such severity as to prohibit their use in humans" (paragraph 0194). In the response received on 10/5/2007, the Applicant's argued in response to the rejection under 35 U.S.C. 103 that it would not be obvious to one

ordinary skill in the art to use high-dose interferon therapy for treatment of pemphigoid because Shachar teaches that high dose interferon is associated with the undesirable side effects discussed above. It is noted, however, that 33,000 and 15,000 units/kg body weight corresponds to 3,300,000 and 1,500,000 IU, respectively, assuming 100 kg body weight as on page 6 of the Applicant's response). Thus, based on the disclosure of Shachar, which teaches that administration of 1,500,000 and 3,300,000 IU IFN-gamma results in unacceptably severe side effects, one of ordinary skill in the art would also predict that administration of the claimed dose range, 2,000,000 – 4,000,000 JRU (which corresponds to 3,000,000 - 6,000,000 IU), would also produce unacceptable, severe side effects. One of ordinary skill in the art would not predict that the claimed invention could be practiced in a manner that would not result in the severe side effects known to be associated with administration of such doses, and would therefore require further, undue experimentation to practice the claimed method in a was that would minimize such risks.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong
Art Unit 1646

/Robert Landsman/
Primary Examiner, Art Unit 1647